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TITLE: Development and Evaluation of a Percutaneous Technique for Repairing Proximal Femora with Metastatic Lesions

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13. Abstract ***(Maximum 200 Words)*** *(abstract should contain no proprietary or confidential information)*
Metastatic lesions in the proximal femur are a common and serious manifestation of breast cancer. These lesions can be painful and can lead to pathological fracture. Prophylactic surgical fixation is advised in patients thought to be at high risk of fracture and typically involves placement of a prosthetic implant or compression hip screw. This study is investigating whether proximal femora with metastatic lesions can be repaired by simply filling the defect with bone cement (polymethylmethacrylate), an innovative procedure that could be performed percutaneously and could eliminate the need for implanting hardware in many cases. If defects could be repaired using this technique, patients would benefit from shorter and less invasive surgical procedures, less pain and discomfort, greatly reduced recovery time, and shorter hospital stays – all at much lower cost. Using finite element (FE) analysis, clinical guidelines for assessing the need for prophylactic fixation and for using the proposed percutaneous procedure will also be developed. To date, materials for testing the proposed repair technique on 12 pairs of cadaveric proximal femora have been identified and obtained. Simulated tumors in 12 femora have been created and repaired. Mechanical testing and FE modeling of these femora to evaluate the technique will begin shortly.

14. SUBJECT TERMS
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Introduction

Metastatic lesions in the proximal femur are a common and serious manifestation of breast cancer. These lesions can be painful and can lead to pathological fracture. Prophylactic surgical fixation is advised in those patients thought to be at high risk of fracture and typically involves placement of a prosthetic implant or a compression hip screw to provide strength. In this study, we are investigating whether proximal femora with metastatic lesions can be repaired by simply filling the defect with bone cement (polymethylmethacrylate), an innovative procedure that could be performed percutaneously and could eliminate the need for implanting hardware in many cases. If the metastatic defect could be safely repaired using this new technique, the patient would benefit from a shorter and less invasive surgical procedure, less pain and discomfort, greatly reduced recovery time, and a shorter hospital stay – all at much lower cost. Using finite element (FE) analysis, this study will also develop clinical guidelines both for assessing the need for prophylactic fixation and for using the proposed percutaneous surgical procedure. This extensive evaluation will enable rapid and safe clinical implementation of the new repair technique and surgical guidelines via a clinical trial immediately following this study.

Body

[Task 1a] Twelve matched pairs of proximal femora were obtained from female donors. Use of femora from female donors was essential because bone density is lower in women than in men and because most breast cancer patients are women.

[Task 1b] A roughly spherical defect was introduced into one randomly selected proximal femur from each pair using a ¼" drill bit and a ¼"-diameter spherical burr. The diameter of each defect measured approximately 75% of the diameter of the neck of the corresponding femur and

was randomly placed in the most inferomedial, superolateral, anterior, or posterior portion of the narrowest part of the neck (three femora with each defect location).

[Task 1c] Before the defects could be repaired, the appropriate equipment and supplies necessary for performing the proposed repair technique had to be identified and obtained. This was a significant aspect of developing the technique and included the following items:

- Stryker Howmedica Osteonics Surgical Simplex® P Radiopaque Bone Cement (one dose per defect)
- Stryker Instruments Advanced Cement Mixing (ACM) system (one per defect)
- Stryker Dual Speed Cement Injector
- Stryker Instruments Thin Flexible Nozzle for use with ACM (one per defect)
- One (1) custom-made cement pressurizer
- Concept Incorporated aiming device (drill guide)
- Drill guide wire
- 4.0-mm, 6.5-mm, and 10-mm extra-length drill bits
- Medi-Vac Flex Advantage 1500 ml suction canister and vacuum trap

The defects were then repaired using the following procedure. The aiming device was used to direct the guide wire through the lateral aspect of the greater trochanter into the defect. The drill hole was then enlarged to 10 mm using a series of drill bits. Debris was removed from the drill hole and defect using a combination of lavage, suction, and compressed air. An arthroscope was used to visualize the interior of the bone to ensure that it was free of debris. The cement was mixed in an ACM system and delivered using the Dual Speed Cement Injector and Thin Flexible Nozzle (6-mm outside diameter). The nozzle was inserted through the drill hole, and the defect and, subsequently, the drill hole were filled with cement. The cement was pressurized using the custom-shaped pressurizer placed over the entrance of the drill hole, while a finger was placed over the cortical defect.

[Task 1d] CT scanning of all 24 bones is scheduled to occur during the first two weeks of May 2003. [Task 1f] FE models will then be generated from the CT scan data, and the bones will be mechanically tested to failure in June 2003.

[Task 1e] The elastic modulus and strength of bone cement in tension and compression have been studied extensively and are readily available (Saha and Paul, 1984), so these mechanical properties will be obtained from journal articles instead of being measured.

Key Research Accomplishments

- Equipment and supplies needed for the proposed repair technique were identified and obtained.
- Twelve matched pairs of cadaveric proximal femora were obtained.
- A defect was created in the neck of one femur from each pair.
- The defects were repaired using the proposed technique.

Reportable Outcomes

The first phase of this project is still in progress, so there are no significant outcomes to be reported at this time.

Conclusions

Conventional surgery to prevent pathological fracture, involving implantation of hardware, is highly invasive. If this study shows that a metastatic defect can be safely repaired percutaneously by simply filling the defect with bone cement, <u>the patient would benefit from a shorter and less invasive surgical procedure with less pain and discomfort, greatly reduced recovery time, and shorter hospital stay – all at much lower cost.</u>

The decision to perform prophylactic fixation is complicated by the inadequacy of tools for identifying patients in need of fixation (Hipp et al., 1995). This study is attempting to address

this issue by providing surgical guidelines based on the structural deficit caused by the lesion. More significantly, the availability of a minimally-invasive alternative to traditional surgical fixation will reduce the reluctance to perform surgical repair in those cases where the need for intervention is unclear.

References

Hipp JA, Springfield DS, Hayes WC: Predicting pathologic fracture risk in the management of metastatic bone defects. Clin Orthop Rel Res 312:120-135, 1995.

Saha S, Pal S: Mechanical properties of bone cement: a review. J Biomed Mat Res 18:435-462, 1984.